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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,151	04/15/2002	Bernard Klein	02021	6370

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,151	KLEIN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

1. Applicant's election with traverse of Group I, Claims 14-22, in the paper filed 2/03/05, is acknowledged. Applicant argues that unity of invention exists between the method of Claims 14-22 and the method of Claims 23 and 24.

This argument is not found persuasive for the following reasons. One method for establishing a lack of unity is to find prior art teaching an invention of the claims. In this instance, the prior art teaches the method of Group I. Accordingly, a lack of unity of invention has been established and restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23 and 24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 14-22 are being acted upon.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

A) The citizenship of Inventor Tarte has not been identified.

4. The specification is objected to. Specifically, Applicant has made several changes/additions to the specification without indicating why said changes would be proper. While it is apparent why the priority data should be added to page 1, or why spelling errors should be corrected, e.g., "apoptic" changed to "apoptotic" at page 12, it is not readily apparent why $\alpha v\beta_3$, has been changed to $\alpha v\beta_3$ (page 5), or μm/ml has been changed to μg/ml (page 12). Also note that the marked up version of the changes at page 7 is incorrect, "by" and "DC" were added, not "mature". Applicant is advised that a proper explanation as to the reasons for each non-readily-apparent change to the specification is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 14-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claim 14, the term "mobilization" is vague and indefinite. While the specification discloses that mobilization may be effected by chemotherapy (page 5), this disclosure does not comprise an actual definition of the term, and Claim 19 indicates that other "mobilization" techniques are encompassed by the limitation.

B) In Claim 17, the inflammatory mediator TNF-α, has already been employed in step 2) of independent Claim 14. Accordingly it is unclear how adding it again further limits the claim.

C) The generic "interleukin" in Claim 20 has no antecedent basis in Claim 14. Claim 14 recites only "an interleukin that blocks differentiation towards the macrophage pathway".

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 14-17 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Under *Vas-Cath, Inc. v. Mahurkar* , 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention, and that the invention, in that context, is whatever is now claimed.

There is insufficient written description to show that Applicant was in possession of a "an interleukin that blocks differentiation towards the macrophage pathway" as recited in Claim 14. While the specification discloses that said interleukins include IL-4 and IL-13, the specification provides no further guidance. Thus, the skilled artisan is left with only a functional description for the identification of the interleukin of the claims. Said functional description alone, absent any hint of the structural features linking the interleukins, comprises an inadequate written description. Likewise the "cell growth factor" of Claim 19 is inadequately described. In this instance no additional description is disclosed for this potentially unlimited genus of factors. Thus, again, no common structural feature has been identified and the written description is considered to be inadequate. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarte et al. (1998, IDS) in view of U.S. Patent No. 5,405,772.

Tarte et al. teaches a method of obtaining dendritic cells (DCs) comprising cultivation of mobilized mononuclear cells (obtained from a multiple myeloma patient who would have had some chemotherapy) in serum-free medium, GM-CSF and IL-4 or IL-13, for 5 days followed by 2 days in TNFα culture (see particularly page 1853, columns 2, *Results*).

The reference teaching differs from the claimed invention only in that it does not teach the cultivation of said cells in human albumin.

The '772 patent teaches that serum albumin, particularly human albumin, is a routine component of serum-free cell culture medium (see particularly column 10, line 66-column 11, line 8),

particularly, hematopoietic cell culture medium (see particularly column 8, lines 17-20).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of obtaining DC of Tarte et al., including human albumin in the cell culture, as taught by the '772 patent. One of ordinary skill in the art at the time of the invention would have been motivated to include human albumin because it was a routine component of hematopoietic cell culture medium, as taught by the '772 patent. Note that the limitations of Claims 20-22 comprise only the routine optimization of the amount of cytokines and albumin used in the culture method and would have fallen well within the purview of the skilled artisan at the time of the invention. Said additional limitations do not render the claimed method patentably distinct.

11. Claim 18 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Tarte et al. (1998, IDS) in view of U.S. Patent No. 5,405,772, as applied to Claims 1-17 and 19-22 above, and in further view of Kalinski et al. (1998, IDS).

Tarte et al. and the '772 patent have been discussed, above. The teachings of the combined references differ from the claimed invention only in that they do not teach the additional use of prostaglandin E2 (PGE2) in the cell culture.

Kalinski et al. teaches that PGE2 synergizes with TNFα in DC cell culture in inducing DC maturation (see particularly page 2805, column 2, *Results*).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform the method of obtaining DC of Tarte et al., including human albumin in the cell culture, as taught by the '772 patent, as well as PGE2, as taught by Kalinski et al. One of ordinary skill in the art at the time of the invention would have been motivated to include PGE2 in the method given the teachings of Kalinski et al. that PGE2 synergizes with TNFα in DC cell culture in inducing DC maturation, thus, providing an improved method for obtaining DC from culture.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier

communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/18/05

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600